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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,920	06/25/2001	Thomas J. Holman	1001.1181102	9756
28075	7590	03/22/2006		
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER HAYES, MICHAEL J	
			ART UNIT 3767	PAPER NUMBER

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,920	HOLMAN ET AL.	
	Examiner	Art Unit	
	Michael J. Hayes	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-46 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 35-39 and 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-29, 35-39, 41-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as filed, did not describe a lumen with a fixed (i.e., not able to be changed or unchanging) diameter along its length and at least a portion of the proximal portion of the hub as recited in amended claims 27 and 41.

Claim Objections

Claim 27 is objected to because of the following informalities: the claim, as currently amended repeats the phrase “at least” in line 7. Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lumen having a substantially fixed diameter extending through the strain relief and a proximal portion (or section) of the hub, as recited in claims 27 and 41 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 29, 35, 36, 37, 38, 39, 41, 42, 43, 44, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIJKAMP et al. (US Patent No. 5,167,647) in view of LONG et al. (US Patent No. 4,632,488). Wijkamp discloses an integral winged catheter tube hub (fig. 1) that can be made as two connected pieces or molded as one piece (col. 1, line 60 - col. 2, line 15) including a proximal portion configured as a flange connector 9, a distal portion 5 configured as a strain relief, a lumen extending through the strain relief and at least a portion of the hub being substantially fixed diameter (i.e., unchanging during use) (fig. 1) and configured to receive a and retain a tube 2. The proximal portion is thicker than the distal portion, Wijkamp does not disclose the strain relief to include a generally helical wall separated by spaces that extend into the lumen where the wall thickness and height decreases distally or that the connector is threaded. Wijkamp is silent concerning the materials of construction of the hub. Long discloses a hub comprising a proximal and distal portions having a strain relief with helical wall with bends separated by spaces 30, the helical wall thickness and height decreases distally and extends from near the proximal end to near the distal end. The lumen is uniform diameter

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though the strain relief and at least partially through the hub (col. 4, ll. 58-61) (See also figs. 3, 5, 11B, 12; col. 4, ll. 54-68; col. 5, ll. 1-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Long in the device of Wijkamp in order to provide a resilient snug fit as discussed in Long (see citations above) and to resist sharp bending and to prevent mechanical fatigue.

Re claims 38 and 39 the use of nylon or PEBA in a medical device is a known use of common medical device materials in a medical catheter hub. The skilled artisan would know to use either of these popular medical device materials for use in a medical device to employ their well known characteristics.

Claims 36 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIJKAMP et al. (US Patent No. 5,167,647) in view of LONG et al. as applied to claim 27 and further in view of PRICHARD et al. (US Patent No. 5,380,301). Wijkamp and Long disclose the claimed device except for use of a threaded connector. Prichard teaches the use of a threaded connector 15. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Prichard in the device of Wijkamp and Long to obtain a secure connecting structure. The skilled artisan would have the knowledge of threaded connectors generally available to make a connection between two pieces as this form of connectors are common throughout connectors in the medical device field as a whole and could choose a threaded connector to allow a connection to another medical device.

Response to Arguments

Applicant argues that support for a fixed diameter through the strain relief and at least a portion of the proximal portion of the hub is found in fig. 2 that “appears” to show a constant diameter (remarks, pg. 5, received 12/29/05). The examiner maintains the rejections under 112(1) above because what the figures “appear” to show does not provide support of a recited limitation added to the claims. Applicant has not pointed to any description of a fixed diameter as recited in the claims, and cannot rely on the figures for undisclosed dimensions.

Applicant argues that Fig. 2 in combination with Fig. 3 and specification shows all the features of a fixed diameter with recited limitations of claims 27 and 41. The examiner does not agree because the specification cited by Applicant states “other than the strain relief 106” (remarks, pg. 5, received 12/29/05). Since the specification states that the strain relief of Fig. 3 is not the same as that shown in Fig. 2 Applicant should not rely on Fig. 2 to show strain relief features.

Applicant argues that Wijkamp does not show a monolithic hub structure. The examiner disagrees and refers Applicant to the description at col. 1, line 60 - col. 2, line 15 of a molding process that results in a monolithic hub structure disclosed in the prior art. Applicant’s remarks concerning the monolithic structure of molded construction is further evidence of the molded construction of the prior art resulting in a monolithic construction.

Applicant argues that there is no motivation to combine Wijkamp with the teachings of Long. The examiner maintains the rejection because Long discloses the use of helical spring design to resist sharp bending and prevent mechanical fatigue (col. 1, ll. 18-21). One of ordinary

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skill in the art would find desirable a design that prevents mechanical fatigue to prevent catheters from leaking and posing a danger to patients.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SUZUKI et al. (U.S. Patent No. 4,682,981) DAVILA, KLUMP, Jr., and LALIKOS (US Patent No. 5,143,409) show a hub with strain relief.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
19 March 2006



**MICHAEL J. HAYES
PRIMARY EXAMINER**